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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,075	03/17/2005	Lajos Szente	OP/4-32464A	9586

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EXAMINER
WEBB, WALTER E

ART UNIT	PAPER NUMBER
1612	

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01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,075	SZENTE ET AL.	
	Examiner	Art Unit	
	Walter E. Webb	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *3,4,8,9,11,12 and 16-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,10 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-28 are pending.

Claims 3, 4, 8, 9, 11, 12, and 16-28 are withdrawn from consideration.

Claims 1, 2, 5-7, 10, and 13-15 are currently under examination.

Election/Restrictions

Applicant's election with traverse of claims 1-28 in the reply filed on November 30, 2007 is acknowledged. The traversal is on the ground(s) that the action fails to allege any grounds under which Groups I, II, III, and V lack unity of invention. This is not found persuasive because the grounds for lack of unity of invention have been established. The requirement for unity of invention is a ***special*** technical feature shared throughout each claimed invention, and these groups lack the ***special*** technical feature. The prior action clearly distinguishes the technical features of each invention.

The inventions of Groups I-III are products by process. The product, the precipitate, in each invention is different since the process adds different elements to yield the product. For example, Group II further adds a pesticide to the product, while Group III changes the type of ammonium-type component of the precipitate to a phospholipid. In Group V, the technical feature is the interaction of the product (of Group II) with the subject *in situ* yielding a pharmaceutical composition. There is no special technical feature shared between these groups. Therefore, the restriction is proper, and is made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-7, 10, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao (US 6,379,692) in view of Szejtli (Journal of Inclusion Phenomena and Molecular Recognition in Chemistry, 1992).

Rao teaches a pharmaceutical composition comprising an active agent that is sparingly soluble in water. (See Abstract.) The composition is in the form of a precipitate comprising an active ingredient by dissolving the active ingredient in a salt solution, forming an acidic dispersion with hydrophilic polymer(s) and a viscosity enhancing agent, then admixing the salt solution and aqueous suspension whereby a precipitate of microparticles are formed. (See, for example, col. 3, lines 23-45; see also Example 1, lines 29-43.) Other ingredients such as preservatives are preferably added to the second, acidic dispersion. (See col. 3, lines 40-43.) They teach that the viscosity-enhancing agent produces acceptable crystal morphology. (See col. 2, lines 38-41.) The viscosity-enhancing agent can be hydroxymethylcellulose or hyaluronic acid or mixtures thereof. (See col. 4, lines 17-24.) The added preservative can be benzalkonium-chloride. (See col. 5, lines 44-49; see also Example 1, lines 29-43.)

Rao, discussed above, differs from the instant claims 2 and 10 insofar as it does not teach incorporation of cyclodextrin into the precipitate.

Szejtli teaches use of cyclodextrins in stable aqueous suspensions for poorly water-soluble drugs. (See Abstract.) Szejtli teaches that the cyclodextrins can be β. (See ibid.)

"It would be prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven 206 USPQ 1069, 1073.

It would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to incorporate cyclodextrin into the precipitate of Rao, since cyclodextrin is well known in the art to be useful in enhancing the solubility of drugs. The artisan would also be motivated to combine the cyclodextrins of Szejtli with the precipitate of Rao, since both compositions are used for enhancing the solubility of poorly soluble compounds. (See Abstract of Rao, and Abstract of Szejtli.)

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rao (*supra*) in view of Szejtli (*supra*) and further in view of Berg et al., (US 5,464,650).

Rao, discussed above, does not teach a method for coating a non-liquid carrier with the precipitate as in claim 15.

Berg et al. teach a method for making an intravascular stent, which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent. (See Abstract.) The polymer can be carboxymethyl cellulose. (See col. 5, line

7.) They teach that metal stents are suitable for drug delivery in that they are capable of maintaining intimate contact between a substance applied to the outer surface of the stent and the tissues of the vessel to be treated. (See col. 2, lines 1-7.)

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to utilize process of Rao to coat the stents of Berg et al. since these stents are successful form of drug delivery to vessels and tissues, and the process of Rao would be ideal for delivering poorly soluble compounds. The artisan would reasonably expect success in utilizing the process of Rao to coat the stents of Berg et al., since the polymer used to coat the stent in Berg et al. can be carboxymethyl cellulose, which is also the viscosity enhancing agent used to form the precipitate of Rao.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
Patent Examiner
AU 1612

Frederick F. Krass
Primary Examiner
AU 1614